Protocol Title: A Randomized, Controlled, Phase II Study of the Activity and Safety of Autologous Gene-Modified Cytotoxic T Lymphocytes in HIV-Infected Patients

Non-technical Abstract:

HIV infection progressively destroys the human immune system and results in AIDS in the majority of patients. There is currently no cure for HIV infection or AIDS. White blood cells called $CD8^+$ T cells kill cells infected with viruses and are an important component of the body's defense against viral infections. Although $CD8^+$ T cells play an important role in temporarily controlling HIV infection, data suggest that a breakdown of the cell response may be responsible for progression to AIDS. Cell Genesys, Inc. has designed a receptor, CD4-zeta, that when expressed on $CD8^+$ T cells will recognize HIV-infected cells and kill them.

In the proposed clinical study, $CD8^+$ T cells will be removed from HIV-infected patients and modified by genetically inserting the gene for the CD4-zeta receptor. The gene-modified cells will be purified and expanded to large numbers in the laboratory before infusion into the patient. In this study, all patients will continue to receive the antiretroviral therapy prescribed by their physician, and half of the patients will also receive gene-modified CD4-zeta $CD8^+$ T cells. This study will evaluate the antiviral activity and safety of CD4-zeta $CD8^+$ T cells. By monitoring immune status, viral burden, organ function, and persistence of the cells in the body, we hope to determine whether this potential therapeutic approach is active and safe.